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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

MSD CONSUMER PRODUCTS, INC., SANTARUS, INC., and THE CURATORS OF THE UNIVERSITY OF MISSOURI, Plaintiffs, v. PAR PHARMACEUTICAL, INC., Defendant.	)	C.A. No. 3:10-cv-04837-MLC-LHG

DEFENDANT PAR PHARMACEUTICAL, INC.'S ANSWER, SEPARATE DEFENSES, AND COUNTERCLAIMS

Defendant Par Pharmaceutical, Inc. ("Par"), by and through its attorneys, for its Answer to the Amended Complaint of Plaintiffs MSD Consumer Products, Inc., Santarus, Inc., and the Curators of the University of Missouri, (collectively "Plaintiffs"), hereby declares as follows:

THE PARTIES

1. Par is without knowledge and information sufficient to form a belief as to the location of incorporation, principal place of business, and corporate parentage of MSD Consumer Products, Inc. Par thus denies the allegations of Paragraph 1.

2. Par is without knowledge and information sufficient to form a belief as to the location of incorporation and principal place of business of Santarus, Inc. Par thus denies the allegations of Paragraph 2.

3. Par is without knowledge and information sufficient to form a belief as to the organizational structure and place of business of The Curators of the University of Missouri. Par thus denies the allegations of Paragraph 3.

4. Par admits it is a corporation organized and existing under the laws of Delaware with a principal place of business at 300 Tice Boulevard, Woodcliff Lake, New Jersey 07677. Par further admits that it is engaged in the manufacturing of, *inter alia*, generic pharmaceutical products in the United States, including in the District of New Jersey. Par denies the remaining allegations of Paragraph 4.

NATURE OF THE ACTION

5. Par admits that the Amended Complaint purports to be a civil action for patent infringement under the patent laws of the United States, Title 35 of the United States Code, of U.S. Patent No. 7,399,772 ("the '772 patent").

JURISDICTION AND VENUE

6. Paragraph 6 states a legal conclusion to which no response is required. To the extent a response is required, Par admits that Plaintiffs purport to base jurisdiction on 28 U.S.C. §§ 1331 and 1338(a). Par denies that it engaged in or is engaging in any act that violates the

patent laws of the United States, and Par further denies that it engaged in or is engaging in any act resulting in liability for patent infringement.

7. Paragraph 7 states a legal conclusion to which no response is required. To the extent a response is required, Par states, for the limited purposes of this action only, that it does not contest personal jurisdiction in this judicial district. Par denies the remaining allegations of Paragraph 7.

8. Paragraph 8 states a legal conclusion to which no response is required. To the extent a response is required, Par admits that Plaintiffs purport to base venue on 28 U.S.C. §§ 1391(b) and (c), and 1400(b). Par does not contest venue in this judicial district for the limited purpose of this action only. Par denies the remaining allegations of Paragraph 8.

THE PATENT

9. Par admits that the '772 patent, on its face, is entitled "Substituted Benzimidazole Dosage Forms and Method of Using Same," and lists the date of issue as July 15, 2008. Par further admits that what appears to be a copy of the '772 patent is attached to the Amended Complaint as Exhibit A. Par denies the remaining allegations of Paragraph 9.

10. Par is without knowledge and information sufficient to form a belief as to assignment and ownership status of the '772 patent. Par thus denies the allegations of Paragraph 10.

11. Par admits that the '772 patent is listed in the United States Food and Drug Administration ("FDA")'s "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book") with respect to ZEGERID OTC. Par is without knowledge and information sufficient to admit or deny the remaining allegations of Paragraph 11 and thus denies the same.

12. Par admits that Santarus, Inc. and the Curators of the University of Missouri previously brought patent infringement lawsuits against Par in the United States District Court

for the District of Delaware. Par further admits that its Abbreviated New Drug Application ("ANDA") sought approval to market generic omeprazole and sodium bicarbonate capsules. The remainder of Paragraph 12 states a legal conclusion to which no response is required. To the extent a response is required, Par states that the District Court's opinion in the previous lawsuit is self-evident with respect to the Court's ruling.

13. Par admits that it filed an appeal to the United States Court of Appeals for the Federal Circuit, which was assigned the Docket Number 2010-1380 and consolidated with the appeal by Santarus, Inc. and The Curators of the University of Missouri, Docket Number 2010-1360. The remainder of Paragraph 13 states a legal conclusion to which no response is required. To the extent a response is required, Par states that the District Court's opinion in the previous lawsuit is self-evident with respect to the Court's ruling.

14. Par admits that Paragraph 14 accurately quotes selected passages of the District Court's ruling. The remainder of Paragraph 14 states a legal conclusion to which no response is required. To the extent a response is required, Par states that the Federal Circuit's opinion is self-evident with respect to the Court's ruling.

ACTS GIVING RISE TO THIS ACTION[1]

15. Par admits that it submitted an ANDA, assigned number 201946, to the FDA pursuant to 21 U.S.C. § 355(j) seeking approval to market omeprazole and sodium bicarbonate capsules in 20 mg/1100 mg dosage strengths, (which capsules are hereinafter referred to as the "ANDA Products"). Par denies the remaining allegations of Paragraph 15.

16. Par avers that on or before August 6, 2010, Par sent to Plaintiffs a notice letter identifying the filing of ANDA No. 201946 by Par. Par avers that this notice letter advised

[1] Headings are reprinted here with the same language as used in Plaintiffs' Amended Complaint, simply for ease of reference, and do not constitute an admission.

Plaintiffs that ANDA No. 201946 contained a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that the '772 patent is invalid or will not be infringed by the commercial manufacture, use, or sale of the ANDA Products. Par denies the remaining allegations of Paragraph 16.

17. Par is without sufficient information to admit or deny the allegations of Paragraph 17 and, therefore, denies the same.

INFRINGEMENT OF THE '772 PATENT

18. No response is required to the general reallegation and incorporation by reference of the allegations of Paragraphs 1-17 of the Amended Complaint. To the extent a response is required, Par hereby incorporates by reference its responses to Paragraphs 1 through 17.

19. Par denies the allegations of Paragraph 19.

20. Par admits that it was aware of the existence of the '772 patent.

21. Par denies the allegations of Paragraph 21.

ANSWER TO PLAINTIFFS' PRAYER FOR RELIEF

Par denies that Plaintiffs are entitled to the relief they seek in Paragraphs (1)–(6) or any relief at all for the allegations made in the Amended Complaint.

SEPARATE DEFENSES

Par pleads the following defenses in response to Plaintiffs' allegations, undertaking the burden of proof only as to those defenses deemed affirmative defenses by law, regardless of how such defenses are denominated herein. Par reserves the right to allege additional defenses in the event that discovery or other analysis indicates that additional affirmative or other defenses are appropriate.

FIRST SEPARATE DEFENSE

22. Each purported claim for relief in the Amended Complaint is barred for failure to

state a claim upon which relief can be granted.

SECOND SEPARATE DEFENSE

23. The claims of the '772 patent are invalid for failing to meet one or more requirements for patentability under Title 35 of the United States Code.

THIRD SEPARATE DEFENSE

24. The manufacture, use, sale, offer for sale, and/or importation into the United States of the ANDA Products does not and will not infringe, induce infringement of, or contribute to the literal infringement of any valid or enforceable claim of the '772 patent.

25. The manufacture, use, sale, offer for sale, and/or importation into the United States of the ANDA Products does not and will not infringe, induce infringement of, or contribute to the infringement of any valid or enforceable claim of the '772 patent under the doctrine of equivalents.

FOURTH SEPARATE DEFENSE

26. Par's actions in defending this case do not constitute an exceptional case under 35 U.S.C. § 285.

RESERVATION OF ADDITIONAL SEPARATE DEFENSES

Par reserves the right to assert additional defenses in the event that discovery or other analysis indicates that additional affirmative defenses are appropriate.

COUNTERCLAIMS

Counterclaimant Par Pharmaceutical Inc. asserts the following counterclaims against MSD Consumer Products, Inc., Santarus, Inc., and the Curators of the University of Missouri, (collectively "Plaintiffs") that U.S. Patent 7,399,772 ("the '772 patent") is not infringed by the

products described in ANDA No. 201946, and/or is invalid for violation of one or more provisions of Title 35 of the United States Code, including 35 U.S.C. § 101 *et seq*.

THE PARTIES

1. Defendant/Counterclaimant Par Pharmaceutical, Inc. is a corporation organized and existing under the laws of Delaware with a principal place of business at 300 Tice Boulevard, Woodcliff Lake, New Jersey 07677.

2. On information and belief, and based on Plaintiffs' allegations, Counterclaim-Defendant/Plaintiff MSD Consumer Products, Inc. is a corporation organized and existing under the laws of Delaware with its principal place of business at 3030 Jackson Avenue, Memphis, Tennessee 38151.

3. On information and belief, and based on Plaintiffs' allegations, Counterclaim-Defendant/Plaintiff Santarus, Inc. is a corporation organized and existing the laws of Delaware, having a principal place of business at 3721 Valley Centre Drive, Suite 400, San Diego, California 92130.

4. On information and belief, and based on Plaintiffs' allegations, Counterclaim-Defendant/Plaintiff The Curators of the University of Missouri is a public corporation and body politic, an arm or instrumentality of state government in the state of Missouri, and has a place of business at 321 University Hall, Columbia, Missouri 65211.

NATURE OF THE ACTION

5. These claims arise under the patent laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. Par Pharmaceutical, Inc. seeks declaration that the '772 patent is not infringed by the products described in Par Pharmaceutical, Inc.'s Abbreviated New Drug Application ("ANDA") No. 201946 and/or is

invalid for failure to comply with one or more provisions of Title 35 of the United States Code, including 35 U.S.C. § 101 *et seq.*

JURISDICTION AND VENUE

6. This Court has subject matter jurisdiction over these Counterclaims for declaratory judgment pursuant to 28 U.S.C. §§ 1331, 1337(a), 1338(a), 2201(a) and (b), and 2202 based on an actual controversy between Par Pharmaceutical, Inc. and Plaintiffs, arising under the patent laws of the United States, 35 U.S.C. §1 *et seq*. This Court has original jurisdiction over the subject matter of these claims under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202 as well as 21 U.S.C. § 355(c)(3)(D).

7. This Court has personal jurisdiction over Plaintiffs based on, *inter alia*, Plaintiffs' filing of this lawsuit in this jurisdiction.

8. Venue is proper in this judicial district based on 28 U.S.C. § 1400(a) and/or 28 U.S.C. § 1391(b), (c), and (d).

BACKGROUND

9. The '772 patent, on its face, is titled "Substituted Benzimidazole Dosage Forms and Method of Using Same" and states its date of issue as July 15, 2008.

10. On information and belief, and based on Plaintiffs' allegations, the patent-in-suit is owned by The Curators of the University of Missouri.

11. On information and belief, Santarus, Inc. is the holder of New Drug Application ("NDA") No. 22-281 for omeprazole and sodium bicarbonate capsules, sold in the United States as ZEGERID OTC.

12. On information and belief, the United States Food and Drug Administration ("FDA") approved NDA No. 22-281 on December 1, 2009.

13. Par Pharmaceutical, Inc. submitted ANDA No. 201946 to the FDA, requesting approval to engage in the commercial manufacture, use, importation, sale, and/or offer for sale in the United States of omeprazole and sodium bicarbonate capsules in 20 mg/1100 mg dosage strengths, before the stated expiration of the '772 patent. Par Pharmaceutical, Inc. made a certification under 21 U.S.C. § 355(j)(2)(a)(vii)(IV) (a "Paragraph IV Certification") that no valid or enforceable claim of the '772 patent would be infringed by the commercial manufacture, use, importation, sale, and/or offer for sale of the products that are the subject of ANDA No. 201946 ("ANDA Products").

14. On October 9, 2012, Plaintiffs filed their Amended Complaint alleging infringement by Par Pharmaceutical, Inc. of the '772 patent.

COUNT I
(Declaration of Invalidity of the '772 Patent)

15. Par Pharmaceutical, Inc. incorporates by reference Paragraphs 1 through 14 of its Counterclaims as if fully set forth herein.

16. The claims of the '772 patent are invalid for failing to meet one or more requirements for patentability of Title 35 of the United States Code, including 35 U.S.C. § 101 *et seq.*

17. A definite and concrete, real and substantial, justiciable controversy exists between Par Pharmaceutical, Inc. and Plaintiffs concerning the validity of the '772 patent, which is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

18. Par Pharmaceutical, Inc. is entitled to a judicial declaration that the '772 patent is invalid.

COUNT II
(Declaration of Noninfringement of the '772 Patent)

19. Par Pharmaceutical, Inc. incorporates by reference Paragraphs 1 through 18 of its Counterclaims as if fully set forth herein.

20. The manufacture, use, sale, offer for sale, and/or importation into the United States of the ANDA Products does not and will not literally infringe, induce infringement of, or contribute to the infringement of any valid or enforceable claim of the '772 patent.

21. The manufacture, use, sale, offer for sale, and/or importation into the United States of the ANDA Products does not and will not infringe, induce infringement of, or contribute to the infringement of any valid or enforceable claim of the '772 patent under the doctrine of equivalents.

22. A definite and concrete, real and substantial, justiciable controversy exists between Par Pharmaceutical, Inc. and Plaintiffs concerning the alleged infringement by the ANDA Products of the '772 patent, which is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

23. Par Pharmaceutical, Inc. is entitled to a judicial declaration that the '772 patent is not infringed.

PRAYER FOR RELIEF

WHEREFORE, Par Pharmaceutical, Inc. requests the following relief:

a) Dismissing Plaintiffs' Amended Complaint with prejudice and denying each request for relief made by Plaintiffs;

b) Declaring all claims of the '772 patent invalid;

c) Declaring all claims of the '772 patent not infringed by the making, use, sale, offer for sale, marketing, or importation into the United States of the ANDA Products;

d) That the 30-month time period referred to within 21 U.S.C. § 355(j)(5)(B)(iii) be shortened to expire immediately;

e) Declaring that this is an exceptional case under 35 U.S.C. § 285 and awarding Par Pharmaceutical, Inc. its attorneys' fees, costs, and expenses in this action; and

f) Awarding Par Pharmaceutical, Inc. such other and further relief as the Court deems just and proper.

Respectfully submitted,

SAIBER LLC
Attorneys for Defendant
Par Pharmaceutical, Inc.

Dated: October 28, 2012

s/ Sean R. Kelly
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LOCAL CIVIL RULE 11.2 CERTIFICATION

Under Local Civil Rule 11.2, the undersigned counsel for Defendant/Counterclaimant Par Pharmaceutical, Inc. ("Par") hereby certifies that this matter is not the subject of any other action asserted by Par in any court, or of any pending arbitration or administrative proceeding.

Dated: October 28, 2012

s/ Sean R. Kelly
Sean R. Kelly

LOCAL CIVIL RULE 201.1 CERTIFICATION

Pursuant to Local Civil Rule 201.1, the undersigned counsel for Par hereby certifies that Par seeks declaratory relief, and therefore this action is not appropriate for compulsory arbitration.

Dated: October 28, 2012

s/ Sean R. Kelly
Sean R. Kelly